

## **Comments on Knowledge Ecology International (KEI), NTIA's request for comments on Big Data and Consumer Privacy**

August 5, 2014

**Docket No. 140514424-4424-01:** Big Data and Consumer Privacy in the Internet Economy. National Telecommunications and Information Administration, U.S. Department of Commerce.

Knowledge Ecology International (KEI) is a non-profit organization based in Washington, DC. Information about KEI is available on the Internet at <http://keionline.org>

KEI offers the following comments on the topic of big data and privacy.

1. Transparency of surveillance activities. To the extent that the public is able to monitor and understand the collection and use of personal information, the more feasible are actions to curb abuses by governments, businesses, and non-profit organizations.
2. KEI cautions against privacy rules that would unduly limit access by legitimate health researchers to information from pharmaceutical clinical trials and other medical records.
3. When a tension exists between privacy and access to such information, there are proposals for expanded uses of regulated trusted intermediaries that can allow legitimate medical researchers the ability to perform queries on sets of data, while shielding identifying information and limiting access to the underlying records. Similar approaches may be needed for other large data sets.
4. KEI is concerned that the US Patent and Trademark Office (USPTO) is granting patents on methods of managing informed consent and privacy of patient records that involve obvious uses of computers to carry out well understood tasks.

Examples of this include several patents recently granted and assigned to Cerner Innovation, Inc., such as:

- 8799006 - System and methods for distributed analysis of patient records
- 8775211 - Methods and systems for managing informed consent processes.
- 8775202 - System and methods for distributed analysis of patient records
- 8756076 - HIPAA-compliant third party access to electronic medical records
- 8682695 - Genetic profiling and banking system and method
- 8706529 - Managing related electronic medical records
- 8239212 - Genetic profiling and banking system and method
- 8117663 - Computerized method and system for restricting access to patient protected health information

Examples from other firms include:

- 8768731 - Syndicating ultrasound echo data in a healthcare environment
- 8606593 - System and method for analyzing, collecting and tracking patient data across a vast patient population
- 8600775 - Enhanced system and method for enhancing and supplementing the informed consent process of a patient undergoing a medical procedure
- 8595028 - System and method for performing medical research across a vast patient population
- 8483966 - Method for increasing utilization of genetic testing

5. While greater protections are likely needed for personal information collected from consumers, the same cannot be said as regards information about businesses and governments. KEI favors fairly extensive transparency regarding the operations of governments, businesses and certain non-profit organizations including information about the individuals working on behalf of those entities.

6. In recent years the National Institutes of Health (NIH) has not been forthcoming or has withheld information regarding lobbying efforts by individuals and firms opposing NIH March-In petitions. The United States Trade Representative has withheld from FOIA requests extensive correspondence between government officials and corporate lobbyists from the motion picture and pharmaceuticals industries.

7. Businesses are allowed to keep secret the amount of money they pay for government-owned patents or federally-funded inventions. Companies selling biologic drugs are allowed to require non-disclosure agreements shielding disclosure of the patents they claim would be infringed by making biosimilar drugs. Nobody in the federal government seems to know or care what companies selling drugs for cancer or other diseases actually invest in R&D for the development of new drugs, even though these costs are the main justification for the high prices of these drugs. There is no disclosure of the amount of money corporations receive from the Orphan Drug Tax credit, even though some other countries routinely disclose the value of such tax subsidies to specific businesses. In these and countless other cases, we would like more disclosure, and not less.